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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
05/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/512,124	CHENG ET AL.	
	Examiner	Art Unit	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,10,20,21,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,10,20,21,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 03 March 2008 has been entered in full. Claims 1-4, 6-9, 11-19, 22-24 have been cancelled and claims 5, 10, 20, and 21 have been amended. Claims 25 and 26 have been added.

Claims 5, 10, 20, 21, 25, and 26 are under examination.

Specification

The objection to the specification has been withdrawn in view of the amendments made to the specification regarding the embedded hyperlink.

Sequence Compliance

According to 37 CFR 1.821(d) (MPEP § 2422), where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. Sequences appear on pages 33, 34, and 47 of the specification but are not identified by SEQ ID NO as required.

Appropriate correction is required.

Rejection Withdrawn

35 USC § 102

Applicant's response and arguments filed on 03/03/2008 have overcome the rejection of claims 20-21 under 35 USC 102(a). The reference by Kawai et al. does not teach contacting

the cell with an imidazoquinoline compound. The rejection of claims 20-21 under 35 USC 102(a) has been withdrawn.

New Claim Objections

Claim 10 is objected to because of the following informalities: claim 10 is dependent on claim 7 that has been cancelled.

Claims 5 and 20 are objected to because it is not clear how much is needed to inhibit viral infection. Please note that the claim amendment "with an effective amount" would obviate this objection.

Appropriate correction is required.

Rejections Maintained

Claim Rejections - 35 USC § 112, Second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 10, 20, and 21 remain rejected under 35 U.S.C. 112, second paragraph, and claims 25 and 26 are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The basis of this rejection is set forth at pages 4-5 of the previous Office action mailed 09/06/2007.

At page 7 of the response, Applicants argue that the pending claims have been amended and now avoid all the recitals at issue in the rejection.

Applicants' response has been considered but has not overcome the rejection made under 35 U.S.C. 112, second paragraph. The claims of the instant application are still indefinite.

(i). As disclose at page 5 of the previous Office action, the phrase "TLR3/TLR4 and IRF3 pathways" in claims 20 and 21 is a relative term which renders the claim indefinite. The phrase " TLR3/TLR4 and IRF3 pathways" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what molecules are encompassed by the phrase.

(ii). The terms "IRF3" and "TRL3/TRL4" in claims 5, 20, and 21 are relative terms which render the claims indefinite. The terms "IRF3" and "TRL3/TRL4" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For instance, claims 5, 20, and 21 use acronyms without first defining what they represent in the independent claims. While the claims can reference acronyms, the material presented by the acronym must be clearly set forth at the first use of the acronym.

Claim Rejections - 35 USC § 112, paragraph (Written Description)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20 and 21 remain are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The reasons for the rejection are set forth at pages 6-8 of the Office action mailed 09/06/2007.

At page 8 of the response, Applicants argue that claims 20 and 21 have been amended and now avoid all the recitals at issue.

Applicants' response has been considered but is not found persuasive. Claim 20 and 21 have not satisfied the requirement for written description because Applicants have not provided any identifying characteristics for the TLR3/TLR4 and IRF3 pathways in the cell that are expected to inhibit viral infection or replication in a cell. Although Applicant discloses the biological activity for the TLR3/TLR4 and IRF3 pathways utilized in the claimed method, Applicant has not provided any information regarding the identifying characteristics of the TLR3/TLR4 and IRF3 pathways that would be expected to inhibit a viral infection or replication in a cell. The specification and the claim fail to disclose any specific identifying characteristics that can be used to identify the TLR3/TLR4 and IRF3 pathways that are expected to inhibit a viral infection or replication in a cell for the claimed method. Thus, applicant was not in possession of the claimed genus and the written description requirement is not satisfied. Please note that the Examiner has determined that even, *arguendo*, the mechanism of inhibiting viral replication were known, Applicants have not demonstrated that imidazoquinoline or poly I:C could be effectively used in such a method.

New issue under *USC § 112, paragraph (Written Description)*

Claims 5, 20, 21, 25, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 5 and dependent claims are drawn to an imidazoquinoline compound. Although Applicant discloses the biological activity for the an imidazoquinoline compound

utilized in the claimed method, Applicant has not provided any information regarding the structural identifying characteristics of the imidazoquinoline compound that would be expected to inhibit a viral infection or viral replication in a cell. The specification and the claim fail to disclose any specific structural identifying characteristics that can be used to identify the imidazoquinoline compound that is expected to inhibit a viral infection or viral replication in a cell in the claimed method.

Therefore, Applicant has not satisfied the requirement for written description because the claimed polypeptide of claim 5 encompasses a genus of imidazoquinolines compound but only structural identifying characteristics for Polyl:C are described. The specification does not provide any description of the special features, which are critical to inhibit a viral infection or viral replication. Furthermore, the specification does not provide any teachings sufficient to one of skill in the art to isolate and identify the imidazoquinoline encompassed by the claims. Thus, Applicants have not provided any structural identifying characteristics or properties of the instant imidazoquinoline compound that would be expected to inhibit a viral infection or viral replication. in a cell such that one of skill would be able to predictably identify the imidazoquinoline compound encompassed by the instant claims.

Based on Applicants' disclosure and knowledge within the art, those of skill in the art would conclude that Applicants would not have been in possession of the claimed genus of imidazoquinoline compound lymphocytes that would be expected to inhibit a viral infection or viral replication. in a cell based on the disclosure of the species that include poly I:C and relevant identifying characteristics. Thus, applicant was not in possession of the claimed genus and the written description requirement is not satisfied.

Claim Rejections - 35 USC § 112 (Enablement)

Claims 5, 10, 20, and 21, remain rejected under 35 U.S.C. 112, first paragraph, an claims 25, and 26 are also remain rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The reasons for the rejection are set forth at pages 6-13 of the Office action mailed 09/06/2007.

The claimed invention is drawn to a method of inhibiting viral infection and replication in a cell and the Examiner has interpreted "in a cell" as in vitro or in vivo. Based on the disclosure of the specification, the Examiner has determined that Applicants is enabled for an *in vitro* method for inhibiting a viral infection or viral replication but not for an *in vivo* method.

Wands factor (iii): the breadth of the claims

At page 9 of the response, Applicants argue that as amended the base claims are drawn to steps of contacting the cell with an imidazoquinoline compound or poly I:C thereby inhibiting a viral infection or replication. These steps are simply performed and do not introduce the concerns identified by the Examiner. With respect to the enablement of the methods as they relate to bacterial infections or replication, the claims as amended now set forth viral infections.

Applicants' arguments have been considered but are not found persuasive. The claims remain excessively broad because Applicants have not provided the structural characteristics for the imidazoquinoline compound that can be used to inhibit a viral infection or viral replication. Without providing structural characteristics of the imidazoquinoline compound, one skill in the art would require undue experimentation because the artisan would not know the

imidazoquinoline compound that can be used to decrease viral infection by stimulating the induction of IRF3.

Wands factor (iv): the amount of guidance presented.

At page 9 of the response, Applicants argue that the specification provides adequate guidance for all manipulations required to practice the invention by disclosing the therapeutic utilities of the compounds and provides and exemplifies simple in vitro tests that are used for screening for the required activity.

Applicants' arguments have been considered but are not found persuasive. While Applicants provide general teachings regarding anti-viral compounds, Applicants have not provided any specific guidance the structural characteristics for the imidazoquinoline compound that can be used to decrease viral infection by stimulating the induction of IRF3. In addition, the specification does not provide any guidance as to how the imizaoquinoline compound or poly I:C can completely inhibit viral infection in a cell by stimulating induction of IRF3. Finally, Applicants have not provided any guidance as to what is encompassed by stimulating the induction of IRF3 in cell during viral infection.

Wands factor (v): Working examples.

At page 9 of the response, Applicants argue that the specification provides a working example of the inhibition of viral replication in Example 5. Poly (I:C)-treated murine bone marrow-derived macrophages were exposed in vitro to murine gammaherpes virus. The treatment was found to greatly inhibit viral replication (see, paragraph bridging pages 41 and 42). Additionally, NIH3T3 cells exposed to IFNalpha produced by the treated macrophages also were able to suppress viral replication (see first full paragraph on p. 42).

Applicants' arguments have been considered but are not found persuasive. It is noted that the term "inhibiting" has been interpreted by the Examiner as meaning that an activity will not occur, i.e. viral infection in a cell will not occur. Although example 5 disclose that poly (I:C) can decrease viral replication in macrophages, Applicants have not provided any example that would completely inhibit the murine gamma herpes virus from infecting any macrophages. Therefore, Applicants have not provided any example for the complete inhibition for a viral infection. In addition, Applicants have not provided any working example for decreasing viral infection with any imidazoquinoline compound by stimulating the induction of IRF3.

Wands factor (viii): quantity of experimentation required

At page 13 of the response, Applicants believe that the amendments to the claims have greatly reduced the amount of experimentation required to practice the invention. The field of the invention is the pharmaceutical arts. A great deal of experimentation is quite routine in this field. It is a field which is largely devoted to the screening and testing of a large number of candidate compounds, compositions and treatments in model systems. In addition, as noted above, the Courts do not require clinical testing to demonstrate utility.

Applicants' arguments have been considered but are not found persuasive. It is noted that the term "inhibiting" has been interpreted by the Examiner as meaning that an activity will not occur, i.e. viral infection in a cell will not occur. One skill in the art would require undue experimentation because one of skill in the art would not be able to have a 100% inhibition for a virus to infect a cell by stimulating the induction of IRF3. Finally, the claimed method would also require undue experimentation because the specification has not provided any structural characteristics for the imidazoquinoline compound that can be used to decrease viral infection by stimulating the induction of IRF3.

Conclusion

No claim is allowed.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
May 19, 2008

/Robert Landsman/
Primary Examiner, Art Unit 1647